

Attorney Docket No. P66226US0
Appln. No. 09/764,990

REMARKS

Claims 20-28, 30 and 31 are presented, hereby.

New claim 30 contains the subject matter of claim 29, revised to more clearly define the subject invention, as explained below.

New claim 31 is dependent on claim 21 and contains additional subject matter described in the specification at page 8, lines 18-23.

Claim 29 was rejected under 35 USC 112, second paragraph, for allegedly being indefinite. Reconsideration is requested in view of claim 30, newly presented hereby in place of claim 29.

Claims 20-29 were rejected under 35 USC 103 for allegedly being unpatentable based on the combined teachings of U.S. Patent No. 6,316,012 B1 (N'Guyen) and U.S. Patent No. 5,952,373 (Lanzendörfer). Reconsideration is requested.

Applicants explained in their Amendment filed June 18, 2002, that the presently claimed invention has a unique feature that patentably distinguishes the cited references, taken separately or in combination. That is, the presently claimed composition is limited to include

a vehicle which is liquid at room temperature and which gels at the temperature of the mucus membrane and which [accordingly] is capable of adhering to the mucus membrane [to which it is applied] because of its gelled stated.

According to the statement of rejection in the instant Office Action, N'Guyen *inherently* teaches the "vehicle" feature recited in the present claims. The statement of rejection is mistaken. First it

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should be stated that N'Guyen and Lanzendörfer are completely silent on such feature or inherent property.

The general disclosure of N'Guyen, col. 1-8, is a mere recitation of all kinds of usual cosmetic and pharmaceutical topical formulations and components. The rejection appears to allege that, based on this general disclosure, the reference inherently teaches the property of being liquid at room temperature and becoming a gel at body temperature. However, this mere compilation includes formulations, for example, lotions, creams, milks and so on, which do not necessarily have the property and, in fact, do not have the aforesaid property.

Further, other kinds of formulations, described in N'Guyen at col. 7, 4th paragraph, such as thickened solutions, gels, ointments, emulsions, vesicular dispersions, pastes etc., cannot be considered as having the property of being liquid at room temperature and becoming a gel at body temperature. The art of making cosmetics uses the various forms of solutions, gels, creams, milks, etc. with the aim that they act in the form in which they are prepared. A solution is a solution and a thickened solution remains a thickened solution.

The mere fact that a composition contains a poloxamer or a thickening agent does not inevitably give the formulation the feature of being liquid at room temperature and a gel at body temperature. Thus, if one considers the general teaching of N'Guyen even assuming, *arguendo*, that some of the compositions disclosed in N'Guyen (such as thickened solutions, gels, ointments, emulsions e.g., creams, milk, and vesicular dispersions) might be formulated to have the aforesaid

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property, it is not inevitable; moreover, it is *prima facie* evident that most of these compositions could never have this property.

The statement of rejection mistakenly relies on the theory of inherency with regard to compositions disclosed in N'Guyen at col. 7, line 8 to col. 8, line 29, as the disclosed compositions are taught as being cosmetic or medical compositions, which act under the form they are made.

For the doctrine of inherency to apply it must be "*inevitable*" from the teachings of the prior art. *In re Wilding*, 190 USPQ 59, 62 (CCPA 1976) (*emphasis added*). "In relying on a theory of inherency, the Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic *necessarily* flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 ((Bd. Pat. App. & Inter. 1990) (*emphasis in original*). Before "the burden shifts," the examiner has "the initial burden of establishing a *prima facie* basis for the alleged inherency." 17 USPQ2d at 1463-64. To base a rejection on what is allegedly inherent in the reference teachings,

the examiner must ... reasonably support the determination that the allegedly inherent characteristic *necessarily* flows from the applied prior art.

17 USPQ2d at 1464 (*emphasis in original*). An argument by the PTO is "not prior art." *In re Rijckaert*, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993). When the

PTO asserts that there is an explicit or implicit teaching or suggestion in the prior art, it must indicate where such a teaching or suggestion appears *in the reference*. ... The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient to establish inherency. ... [S]uch a retrospective view of inherency is not a

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substitute for some teaching or suggestion supporting an obviousness rejection.

28 USPQ2d at 1557 (*emphasis added*). A "retrospective view of inherency is not a substitute for some teaching or suggestion which supports the selection and use of the various elements in the particular claimed combination." *In re Newell*, 13 USPQ 2d 1248, 1250 (Fed. Cir. 1989).

The general teaching of N'Guyen encompasses all kinds of formulations, which would not inevitably have the property at issue. There is no teaching or suggestion of such property in the reference, nor is there any teaching or suggestion that identifies which ones of all those described would have the property. Therefore, the general teachings of the reference relied on fail to support the alleged inherency of the missing property..

Furthermore, none of the examples inherently teaches or suggest the missing property.

Example 1 - This is a classical oil-in-water emulsion with a tensio-active system being polyethylene glycol mono stearate and diglycerol mono/distearate and a thickening agent, namely cetylalcohol. Such emulsion which is of relatively thick consistence (it is as a cream) would become more fluid at higher temperature as would all classical cosmetic creams.

Example 2 - It discloses a very classical fluid emulsion having as gelifying and stabilizing agent Carbopol 940 which is well known in the field of cosmetics. These emulsions are not thermogelifying but, on the contrary, become more fluid at body temperature to be easily applied on the skin.

The same is true for Example 3, which is a classical oil-in-water emulsion with the well known Carbopol 941.

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Example 4 deals with a body cream having the usual ingredients of such cream. None of the ingredient combinations would allow it to have the inherent property objected by the Examiner.

The same is true for Example 5.

Example 6 is for dermo-pharmaceutical cream which also uses the well known thickener Carbopol 941 and it is obvious liquid at temperatures of 70° C. Mixing at higher temperature is also good indication that the mixture is not intended to be more viscous at high temperature.

Example 7 is for a dermo-pharmaceutical gel. The compounds are mixed at room temperature and form a gel. It means that it cannot be liquid at a room temperature and form a gel. It means that it cannot be liquid at a room temperature.

Example 8 is for a protective care cream. The mixture is formed at 80°C. The composition forms a cream which is applied to the face. Such a cream would obviously not gelify at body temperature.

Accordingly the theory of inherency cannot be relied on to sustain the rejection under §103(a). As such, withdrawal of the rejection is in order.

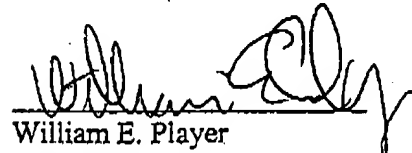
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Favorable action is requested.

Respectfully submitted,

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